

POSTSCRIPTS

Volume III Issue 11
February 2013



POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the newsmagazine of the American Medical Writers Association Pacific-Southwest (AMWA Pac-SW) chapter. It publishes news, notices and authoritative articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical/regulatory writing, scientific writing, publication planning, social media, current regulations, ethical issues, and good writing techniques.

MISSION STATEMENT

The mission of Postscripts is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, Postscripts publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; book and journal summaries. Second, to promote career and networking needs of members, Postscripts includes news and event notices covering Chapter activities.

EDITOR

Ajay K Malik, PhD
ajay@amwa-pacsw.org

EDITOR-AT-LARGE

Jenny Grodberg, PhD, RAC
President, AMWA PacSW
president@amwa-pacsw.org



SUBSCRIPTION

Postscripts is published monthly from February to December. Subscription is included in the AMWA Pac-SW chapter membership which is automatic for all AMWA members with a mailing address in Southern California, Southern Nevada and all of Arizona. This newsmagazine is distributed on the 1st of each month. AMWA members can request past issues by sending an email to the editor.

INSTRUCTION FOR CONTRIBUTORS

We welcome contributions from members and non-members alike.
Please contact editor.

ADVERTISING

Postscripts is an advertisement-free publication. However, articles describing products and services relevant to medical writers may be considered or solicited. Contact editor.

**American Medical Writers
Association
Pacific Southwest Chapter**
(AMWA Pac-SW)
San Diego, CA
www.amwa-pacsw.org

Copyright 2012-2013, AMWA Pac-SW

All rights reserved.

(Authors retain copyright to their articles.)

POSTSCRIPTS

February 2013 | Volume 3, No. 11

FEATURES

- Kathy Boltz* **8** Challenges and Opportunities for Medical Writers Covering Scientific Meetings: a Postcard from San Antonio Breast Cancer Symposium
- Haripriya Shankar* **11** Sirturo™: A new drug to treat multi-drug resistant pulmonary tuberculosis

DEPARTMENTS

- Sally Altman, Kelly Dolezal (FDA updates)* **5** What's UP(!). . . at FDA and EMA
- Wim D'Haeze (EMA updates)* **6**
- Susan Chang* **9** de-MS-tifying Word
- Dikran Toroser* **10** AMA-zing Style
- Irene Yau* **16** Meet my friend C.A.R.L.
- Jennifer Grodberg* **4** From the President's Desk
- 18** Four Sporting Boys: Basketball (Backpage)

REPORTS

- Catherine Kolonko* **13** Meeting Report: Using LinkedIn as a Business Development Tool
- 15** Pictures from the AMWA Pac-SW Holiday Party, December 2012

IMPORTANT DATES

February 28, 2013. Deadline to submit program/session proposal for 2013 AMWA Annual Conference, to be held November 6-9, in Columbus, OH

March 16, 2013. AMWA Pac-SW Chapter's Annual Outreach Event at Amgen, Thousand Oaks

April 28 – May 1, 2013. AMWA Pacific Coast Conference

CHAPTER CONTACTS

President:

Jenny Grodberg
president@amwa-pacsw.org

Immediate Past President:

Noelle Demas
past-president@amwa-pacsw.org

Treasurer:

Valerie Breda
treasurer@amwa-pacsw.org

Arizona Liaisons:

Kathy Boltz
az-liaison-1@amwa-pacsw.org
Mary Stein
az-liaison2@amwa-pacsw.org

Membership Coordinator:

Gail Flores
membership-coordinator@amwa-pacsw.org

Employment Coordinator:

Irene Yau
employment-coordinator@amwa-pacsw.org

Website Communications:

Mary Wessling
mnw@wessling.com

Postscripts Editor:

Ajay Malik
ajay@amwa-pacsw.org

From the President's Desk

Greetings Friends and Colleagues,

2013 is in full swing and so is the AMWA Pacific Southwest Chapter! January was brought to a “happy” close at a January 30 social/networking gathering in San Diego. We’ll be celebrating February with a meeting on February 23 at the University of Arizona library, discussing new programs in PubMed and search options, and also in the making is a Chapter WebEx on publication planning (stay tuned for details). Thanks to the tremendous effort and generosity of our Amgen colleagues, a medical writer open house will take place on the Amgen campus March 16. And last, but by no means least, registration is underway for the 2013 Asilomar Conference (April 28-May 1)! The conference planning committee is hard at work on the details of what should be a wonderful learning and networking opportunity in truly beautiful surroundings! A big THANK YOU to Sharon Dana (conference co-director), Robin Weaver (conference registrar), Valerie Breda (treasurer), Noelle Demas and Linda Kester for their amazing energy and dedication to this effort.

To the many **Postscripts** contributors who continue to educate us in a truly engaging fashion I also say THANK YOU!

Warmly,

Jenny

What's Up(!) . . . at FDA and EMA

FDA updates compiled by: Sally Altman and Kelly Dolezal

At the beginning of this new year, the FDA has enacted several new policies to protect public health. The Medical Device Innovation Consortium and the Food Safety Modernization Act are both newly initiated, and the FDA has developed new guidance documents to deter prescription drug abuse. Routine regulation by the FDA continues to mitigate potentially dangerous issues; many sleep-aid users will follow the FDA recommendation to decrease their dosage of zolpidem after it was found that previously accepted dosages impair alertness the morning after use.

Selected FDA Announcements

- 12/03/2012 The FDA announced its participation in the Medical Device Innovation Consortium (MDIC), the first public-private partnership, which will fund efforts to simplify medical device design and marketing.¹
- 12/17/2012 Performance Plus Marketing, Inc. issued a voluntary recall of multiple products which were found to contain sulfoildenafil and thioildenafil, unapproved analogues of the male-erectile dysfunction drug sildenafil, which likely have similar risks of interaction with prescription drug compounds like nitroglycerin²
- 12/20/2012 Invacare Corp. will halt manufacturing of wheelchairs and wheelchair components until it corrects violations to the FDA's quality systems regulations.¹
- 12/21/2012 Sunland, Inc. has been barred from processing or distributing peanut products following a lack of assurance that problems with products linked to a Salmonella Bredeney outbreak have been corrected.¹
- 01/04/2013 Two rules implementing the Food Safety Modernization Act (FSMA) have been proposed by the FDA, which encourages public comment for the next 120 days.¹
- 01/09/2013 The FDA drafted a guidance document to develop abuse-deterrent formulations of prescription opioids.¹
- 01/10/2013 Sleep aids containing the compound zolpidem are required to lower recommended dosages after studies show levels the morning after use may impair alertness.¹

Selected FDA Approvals

Date	Drug	Indication	Company
11/29/12	Cometriq ³	Metastasis in patients with medullary thyroid cancer	Exelixis
12/14/12	Signifor ³	Cushings disease	Novartis
12/14/12	Iclusig ³	Chronic myeloid leukemia and Philadelphia chromosome positive acute lymphoblastic leukemia	Ariad Pharms
12/14/12	Raxibacumab ³	Inhalational anthrax	Human Genome Sciences
12/21/12	Gattex ³	Short bowel syndrome	NPS Pharms
12/21/12	Adasuve ³	Schizophrenia or bipolar I disorders	Alexza Pharms.
12/26/12	Juxtapid ³	Homozygous familial hyper- cholesterolemia	Aegerion Pharms. Inc
12/28/12	Sirturo ³	Multidrug-resistant pulmonary tuberculosis	Janssen Therapeutics
12/31/12	Fulyzaq ³	Non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy	Salix Pharms
01/14/13	Uceris ³	Mild to moderate ulcerative colitis	Santaris
12/20/12	Topotecan ³	Small cell lung cancers or carcinoma of the cervix	Teva Pharms

¹ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/>

² <http://www.fda.gov/Safety/Recalls/ucm332697.htm?source=govdelivery>

³ <http://www.fda.gov/NewsEvents/ProductsApprovals/default.htm>

What's Up(?) . . . at FDA and EMA

EMA Updates compiled by: Wim D'Haese

EUROPEAN MEDICINES AGENCY (EMA) ALERTS (17 NOV 2012 THROUGH 18 JAN 2013)

The alerts listed below cover the period from November 17, 2012 through January 18, 2013. Only key alerts thought to be of interest to the AMWA community were included; for additional updates and details refer to [What's New](#) on the EMA website.

GUIDELINES

- Guideline on the evaluation of anticancer medicinal products in man (effective date: 01 Jul 2013).^a
- Guideline on the investigation of drug interactions (effective date: 01 Jan 2013).^b
- Draft guideline on pharmaceutical development of medicines for paediatric use (open for public consultation).^c
- Draft guideline on clinical investigation of medicinal products in the treatment of lipid disorders (open for public consultation).^d
- Draft guideline on nonclinical and clinical development of similar biological medicinal products containing recombinant human insulin and insulin analogues (open for public consultation).^e
- Multiple updates on guidelines related to good pharmacovigilance practices.^f
- Draft guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (open for public consultation).^g
- Draft guideline on the clinical investigation of hepatitis-B immunoglobulins (open for public consultation).^h

REPORTS/PAPERS

- Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice Compliance problems.ⁱ
- Reflection paper on considerations given to designation of a single stereo isomeric form (enantiomer), a complex, a derivative, or a different salt or ester as new active substance in relation to the relevant reference active substance.^j

APPROVALS/REFUSALS

Compound	Indication/Use	Applicant	Advice [Note]
• Kynamro ^k	This product was expected to be used for the treatment of patients with an inherited disease causing high blood cholesterol levels, i.e., familial hypercholesterolaemia.	Genzyme Europe B.V.	Negative opinion
• Adasuve ^l	Indicated for the rapid control of mild-to-moderate agitation in adult patients with schizophrenia or bipolar disorder.	Alexza UK Ltd.	Positive opinion
• Fanaptum ^m	This product was expected to be used for the treatment of schizophrenia in adults.	Vanda Pharmaceuticals Ltd. (Washington, DC)	Negative opinion
• Selincro ⁿ	In combination with psychosocial support focused on treatment adherence and reduction of alcohol consumption, intended to reduce alcohol consumption in adults with alcohol dependency.	Lundbeck	Positive opinion
• Lyxumia ^o	Injection for the treatment of Type 2 diabetes mellitus in adults to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycaemic control.	Sanofi-Aventis Groupe (France)	Positive opinion
• Bexsero ^p	Immunisation of individuals from 2 months of age and older against invasive meningococcal disease caused by <i>Neisseria meningitidis</i> group B.	Novartis Vaccines and Diagnostics (Switzerland)	Positive opinion
• Zaltrap ^q	In combination with chemotherapy, indicated in adults with metastatic colorectal cancer that is resistant to or has progressed after an oxaliplatin-containing regimen.	Sanofi-Aventis Groupe (France)	Positive opinion

Note: "positive" or "negative" opinion indicates the Committee for Medicinal Products for Human Use (CHMP) adopted a positive or negative opinion in regards to granting the marketing authorization, respectively, awaiting a final decision of the European Commission (EC).

GENERAL ANNOUNCEMENTS

- The EMA makes eSubmission Gateway release II and eSubmission web client available to applications for centralized marketing authorization for human medicines.^r
- The EMA reviews its operations and processes in light of a reorganization in 2013.^s
- European Medicines Agency announced new advice on safer use of fibrin sealant spray applications.^t
- Reminder to applicants regarding requirements for future eCTD submissions, which came into effect on 01 Dec 2012.^u

LINKS:

- a. http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500137128 [Link]
- b. http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500129606 [Link]
- c.
- http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500137023&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc [Link]
- d.
- http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500136391&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc [Link]
- e.
- http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500136392&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc [Link]
- f. http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000345.jsp&mid=WC0b01ac058058f32c [Link]
- g.
- http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500135705&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc [Link]
- h.
- http://www.ema.europa.eu/ema/doc_index.jsp?curl=pages/includes/document/document_detail.jsp?webContentId=WC500135704&murl=menus/document_library/document_library.jsp&mid=0b01ac058009a3dc [Link]
- i. http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500135113 [Link]
- j. http://www.ema.europa.eu/ema/pages/includes/document/open_document.jsp?webContentId=WC500134993 [Link]
- k. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002429/smops/Negative/human_smop_000460.jsp&mid=WC0b01ac058001d127 [Link]
- l. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002400/smops/Positive/human_smop_000456.jsp&mid=WC0b01ac058001d127 [Link]
- m. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002371/smops/Negative/human_smop_000459.jsp&mid=WC0b01ac058001d127 [Link]
- n. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002583/smops/Positive/human_smop_000458.jsp&mid=WC0b01ac058001d127 [Link]
- o. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002445/smops/Positive/human_smop_000448.jsp&mid=WC0b01ac058001d127 [Link]
- p. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002333/smops/Positive/human_smop_000447.jsp&mid=WC0b01ac058001d127 [Link]
- q. http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002532/smops/Positive/human_smop_000445.jsp&mid=WC0b01ac058001d127 [Link]
- r. http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/01/news_detail_001692.jsp&mid=WC0b01ac058004d5c1 [Link]
- s. http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/12/news_detail_001682.jsp&mid=WC0b01ac058004d5c1 [Link]
- t. http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/12/news_detail_001674.jsp&mid=WC0b01ac058004d5c1 [Link]
- u. http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/12/news_detail_001671.jsp&mid=WC0b01ac058004d5c1 [Link]

Challenges and Opportunities for Medical Writers Covering Scientific Meetings: a Postcard from San Antonio Breast Cancer Symposium

By Kathy Boltz, PhD

Attending medical meetings is always a great opportunity to emerge from my home office, work in-person with my client, perhaps chat with existing clients, network for new opportunities, and thoroughly mix up my daily routine. This past December, I attended the San Antonio Breast Cancer Symposium, the largest meeting of breast cancer professionals from around the world. This meeting had about 7,000 attendees, with half of them from outside the US. Covering a big meeting like this one is a challenge, but is also full of opportunities.

A medical writer's days at a medical conference can vary widely. For example, at this meeting, depending upon the subject areas assigned by my client, my day-to-day schedule varied a lot. One day I was assigned to a continuous coverage, from 7 am to 7 pm. Another day I had no sessions to formally report on, but I had sessions to cover the previous day and the following day. The key is to use this downtime wisely as a real window of opportunity.

During my downtime at the conference, I walked through the exhibitor area to hand out my business cards, and I managed to pursue a contact for a feature article for another client—I had emailed this organization twice so I could include their perspective in my upcoming article, but the generic email on their website yielded no response. After I stopped at their booth for five minutes, explained my article, and wrote a short note on my business card, I received a phone call from the right person from this organization on the very next day. Fortunately, when that phone call came in, I was in my hotel room, so I could quickly take notes. Developing new client relationships is equally important as covering a meeting for an existing client, and finding ways for face-to-face interactions are the most effective way to achieve this.

Attending sessions and viewing posters provide another

strategy to open new doors. Latest clinical trials, particularly early-stage testing of new treatment paradigms, almost always appear as posters, along with the latest research pointing to tomorrow's drugs or disease mechanisms of actions. This current research can yield novel ideas for new feature articles to pitch to editors after you return home. "Therefore, Always Take Copious Notes." When meetings are large, as this one, it is physically impossible to soak up every nugget of information, or even attend every session.

However, some keyword searching of the electronic schedule and online abstracts' database should help in planning an effective schedule.

Finally, let your colleagues know about your travel to the meeting on LinkedIn. Sharing an update, through the box near the top of your homepage, offers more than subtle benefits. Your networked colleagues might also be attending the same conference, so you can connect there and renew your friendships and professional relationships. Also, these updates allow others on LinkedIn know that your expertise is up-to-date. This may yield future work in the therapeutic area of the conference.

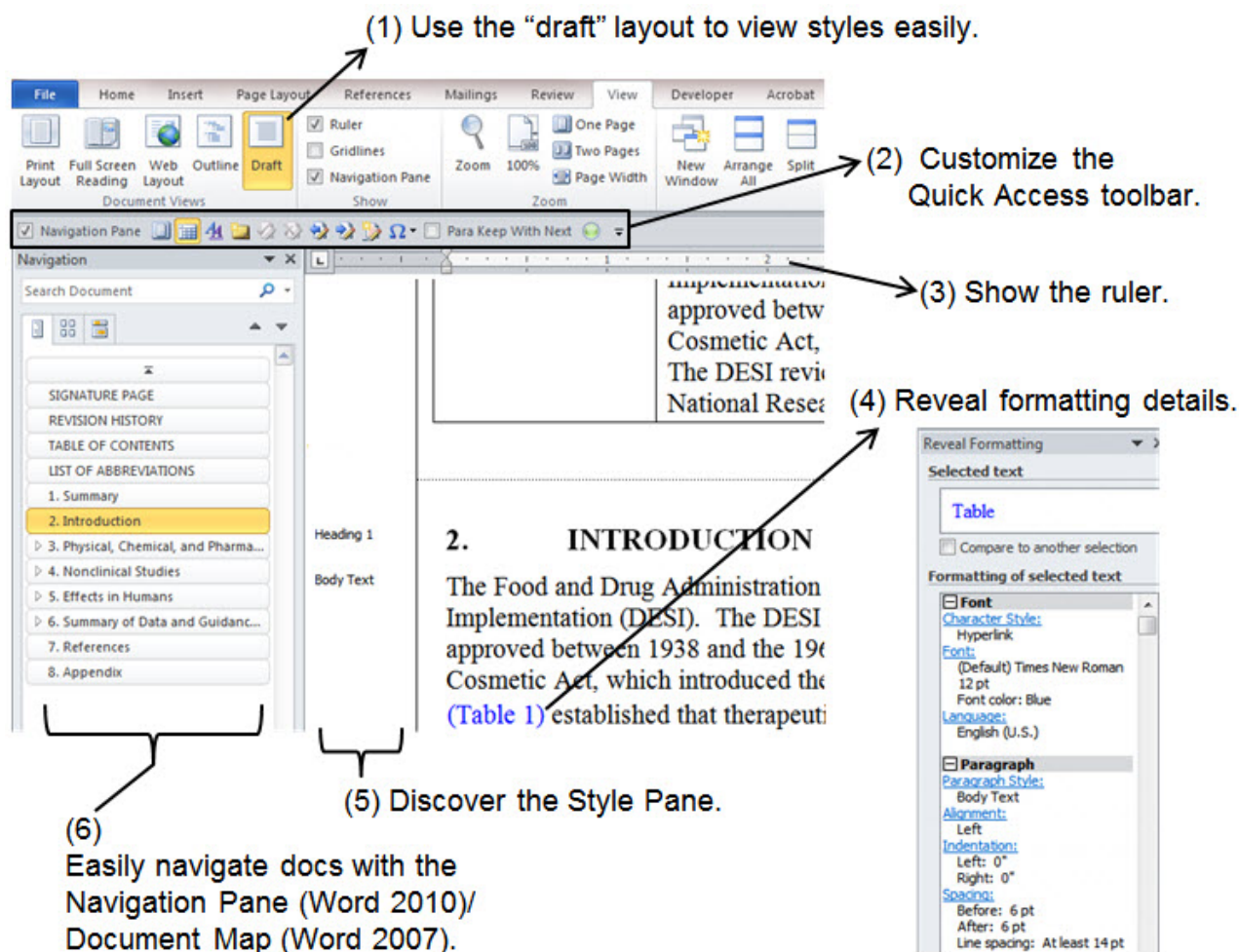


"Real conversations require concentration, not texting on the side. The art of travel demands the end of multitasking. It demands the absence of bars on your smartphone when you are in a café with someone. That's because travel is linear—it is about only one place or a singular perception at a time." —Robert D. Kaplan. *Atlantic Magazine*, Nov 2012.

de-MS-tifying Word

By Susan Chang

Happy New Year! It may be closer to Valentine's Day, but I'm still in a New Year state of mind! Start out the year with a few new tricks to view, navigate, and troubleshoot formatting problems.



1	View tab → Doc Views → choose Draft layout (2010) File → Options → Quick Access Toolbar	See the Style Pane here (refer to #5).
2	(2007) Office Button → Word Options → Customize Quick Access Toolbar	Change placement (above/ below the ribbon) and add/remove your favorite commands!
3	(2010) View tab → Show/Hide → check Ruler (2007) View tab → Show → check Ruler	Change tab spacing, margins, and table column widths on the ruler.
4	Select text → SHIFT + F1	Use hyperlinks here to quickly access and modify formatting settings.
5	(2010) File → Options → Advanced (2007) Office Button → Word Options → Advanced	Set the Style Area Pane width >1.0" to see formatted paragraph styles in Draft view (doesn't work for tables).
6	(2010) View → Show → Check Navigation Pane (2007) View → Show/Hide → Check Doc. Map	Quickly navigate large document with formatted headings/subheadings.

Word woes? Email me at SKC@SusanChangConsulting.com with your MS Word questions!

Type a question for help

AMA-zing style — the AMA manual of style column

By Dikran Toroser, PhD, Amgen Inc.

STUDY DESIGN, STATISTICS and TYPES of STUDY

The AMA manual of style provides some useful insights into statistical analyses and study design. Below is some guidance on the placement of statistical information and study design in publications. Text in *italics* represent concepts further defined in the AMA manual.

THE MANUSCRIPT: Each subsection of the manuscript should contribute to the understanding of why and how the study was done. Some essential elements are: (1) clearly stated hypothesis, (2) appropriate methods to answer the question, (3) credible results, and (4) appropriate implications and the limitations.

ABSTRACT and INTRODUCTION: The study question and the objective should be stated, the design and population described, and outcome measures explained. The results should include the effect size, with *point estimates* and *confidence intervals*. Abstracts are too brief for a detailed explanation of statistics, but a basic description may suffice. The introduction should include a concise literature review and rationale for the choice of a particular method. The study hypothesis or purpose should be stated.

METHODS: The “Methods” section should include enough information to replicate the study. Components of the methods include:

- Study design
- Disease or condition
- *Inclusion and exclusion criteria*
- *Intervention(s), including their length*
- Outcomes and how they are measured, including *reliability* of measures. Whether *blinded* or not
- Statistical methods used for each analysis
- If registered in a central trial registry, registry name and trial number

RESULTS: These should include the number of individuals initially eligible, those excluded, dropped out, or lost to follow-up. Primary and secondary outcome measures should be discussed. *Post hoc analyses* may be presented, but must be identified. Tests of relative results (eg, *relative risk*, *odds ratio*) may overstate the real magnitude of differences—hence, the authors should report the central tendency (ie, mean or median).

DISCUSSION: Whether the hypothesis was supported should be stated. Limitations, especially sources of *bias*, should be discussed. Implications and specific directions for future research may be offered. The conclusions should not go beyond the data and should be based on the study results and limited to the specific *population* represented by the study *sample*.

RANDOMIZED CONTROL TRIALS. The randomized control trial (RCT) provides the strongest evidence for the efficacy of a treatment. The methods must be described to allow judgments of quality, allow replication, and extract pertinent information for comparison with other studies. The CONSORT statement¹ provides a checklist to help ensure complete reporting of RCTs.

OBSERVATIONAL STUDIES. In these, the researcher identifies a condition or outcome of interest and then measures factors that may be related to that outcome. Observational studies cannot lead to strong causal inferences, but may suggest certain causal hypotheses. There are currently no universally accepted guidelines for reporting observational studies. However, the CONSORT group is currently developing appropriate guidelines. The STROBE statement² (<http://www.strobe-statement.org/>) may be helpful.

META-ANALYSIS: Meta-analysis is a pooling of the results of 2 or more studies. According to Moher and Olkin³, meta-analyses provide a method for synthesizing a quantitative overall estimate derived from the individual studies. To help standardize the presentation of meta-analysis, JAMA recommends use of the QUOROM³ flow diagram and checklist for meta-analyses of RCTs, and the MOOSE⁴ checklist for meta-analyses of observational studies.

REFERENCES

1. Moher D *et al.*, Consort 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *Int J Surg*. 2012;10:28-55
2. von Elm E *et al.*, The strengthening the reporting of observational studies in epidemiology (strobe) statement: Guidelines for reporting observational studies. *J Clin Epidemiol*. 2008;61:344-349
3. Moher D, Olkin I. Meta-analysis of randomized controlled trials. A concern for standards. *JAMA*. 1995;274:1962-1964
4. Stroup *et al.*, Meta-analysis of observational studies in epidemiology: A proposal for reporting. Meta-analysis of observational studies in epidemiology (moose) group. *JAMA*. 2000;283:2008-2012

See pages 835 to 905 in the AMA Manual of Style 10th edition for additional information.

Sirturo™: A new drug to treat multi-drug resistant pulmonary tuberculosis

By Haripriya Shankar, PhD

The Food and Drug Administration (FDA) approved SIRTURO™ (bedaquiline) in December 2012 for the treatment of multi-drug resistant pulmonary tuberculosis (TB). Sirturo was approved for use in adult patients (≥ 18 years) as a part of combination therapy in the absence of other effective treatment options.¹

Tuberculosis, a potentially fatal disease, is caused by *Mycobacterium tuberculosis*. It is transmitted from one person to another through air and primarily affects the lungs, but other organs including the kidneys and brain may also be affected. The symptoms are often non-specific—such as cough, fatigue, and weight loss—delaying diagnosis and treatment. High prevalence of the multi-drug resistance strains further complicates treatment management.

According to the Centers for Disease Control and Prevention (CDC), approximately 9 million people across the globe were infected with TB in 2011 and currently, one third of the population worldwide is infected with TB. TB is a serious public health problem in the less-developed countries, particularly in Africa, due to the existence of comorbidities such as AIDS; HIV infection weakens the immune system and predisposes the patient to TB infection. While there has been a significant progress toward eliminating TB in the United States and the western world, it remains a major public health concern worldwide in the developing countries.²

According to the Centers for Disease Control and Prevention, “*Drug-resistant TB is caused by organisms that are resistant to at least one first-line anti-TB drug, whereas multi-drug resistant TB is caused by an organism that is resistant to isoniazid and rifampin, the two most potent anti-TB drugs*”. The drug-resistant forms of TB are complicated and difficult to treat.

The FDA accelerated the approval of Sirturo because of its potential to kill this deadly form of bacteria; however, larger well-controlled studies/clinical trials need to be

conducted to test and verify its clinical benefit in broader population.³ Sirturo belongs to a new class of anti-mycobacterial drugs and was developed by the scientists at Janssen Therapeutics. It kills *Mycobacterium tuberculosis* by inhibiting mycobacterial ATP synthase, an enzyme that is necessary for the generation of energy within the organism.⁴

As described in the recent FDA News Release, “*Sirturo’s safety and effectiveness were established in 440 patients in two Phase 2 clinical trials. Patients in the first trial were randomly assigned to be treated with Sirturo plus other drugs used to treat TB, or a placebo plus other drugs used to treat TB. All patients in the second trial, which is ongoing, received Sirturo plus other TB drugs. Both studies were designed to measure the length of time it took for a patient’s sputum to be free of *M. tuberculosis* (sputum culture conversion, or SCC). Results from the first trial showed patients treated with Sirturo combination therapy achieved SCC in a median time of 83 days, compared with 125 days in patients treated with placebo combination therapy. Results from the second trial showed the median time to SCC was 57 days, supporting the efficacy findings of the first trial. Common side effects identified in the clinical trials include nausea, joint pain, and headache.*”⁵

Sirturo is not indicated for treating latent, extra-pulmonary, or drug-sensitive TB. A black box warning for patients and health care professionals has been included in the product label because an increased risk of death was noted in the Sirturo group (11.4%) compared to the placebo group (2.5%). Sirturo can also prolong the QT interval (electrical activity of the heart), and therefore, an ECG should be obtained prior to use. Therefore, physicians should prescribe Sirturo only when other effective treatment regimens cannot be provided.⁴

The development of Sirturo is a major breakthrough

(continued on next page)

because it provides an alternative to treat millions of patients all over this world who suffer from multi-drug resistant TB.

REFERENCE AND WEBLINKS:

1. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333695.htm>
2. <http://www.cdc.gov/tb/topic/globaltb/role.htm>
3. http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2012/204384Orig1s000ltr.pdf
4. Sirturo label: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/204384s000lbl.pdf
5. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333695.htm>

FURTHER READING

- F.D.A. Approves Drug for Resistant Tuberculosis. Thomas K. New York Times [online]. December 31, 2012. Available at: <http://www.nytimes.com/2013/01/01/business/fda-approves-new-tuberculosis-drug.html>
- <http://www.janssentherapeutics.com/sites/default/files/pdf/PressRelease12312012.pdf>

###



The 2013 AMWA Annual Conference Wants You!

Share your expertise at the 2013 AMWA Annual Conference, to be held November 6-9, in Columbus, OH. New this year is a Call for Program Proposals for all types of sessions, including several new session formats. You can learn more about these formats and about how to submit a high-quality proposal on the AMWA website. Presenting a session at the Annual Conference offers several benefits! For example, you can establish yourself as an expert in your field, refine your presentation techniques, and help grow your subspecialty; in addition, many employers will pay for conference attendance only if the employee presents.

Expand your horizons and plan to present in Columbus! The deadline to submit proposals is February 28, 2013.

Meeting Report: Using LinkedIn as a Business Development Tool

By Catherine Kolonko

“LinkedIn is about connecting talent with opportunity,” says speaker John Rodolff, repeating the words of the website CEO Jeff Weiner

If you want to shine a light on your talents and uncover hidden career opportunities, a good place to start is with a polished profile on LinkedIn, according to John Rodolff of Venture Builder, guest speaker for the November meeting of the American Medical Writers Association Pacific Southwest Chapter held in Carlsbad, CA.

One of the first tasks for those striking out on their own in the business world is to create a marketing and promotional plan that maps out goals and the strategies to achieve them. The same sort of action plan benefits anyone who wants to succeed in business, even the person who works at a large corporation, says Rodolff. Think of yourself as “Me Inc.” he advises and always have a brief “elevator pitch” that highlights your talents and successes.

LinkedIn is a great promotional tool and its company leaders describe it as a place to showcase your business, reach new customers and attract great talent, says

Rodolff. While he mainly focused on efficient use of LinkedIn, Rodolff also mentioned other internet avenues that lead to building business presence, such as the high profile sites Twitter and Facebook. In addition, self-produced podcasts offer a two-lane approach of educating others and building name recognition.

While they are sometimes lumped together as social media, Rodolff differentiates LinkedIn from Facebook. Generally, the first is best suited for professional interaction and business networking while the latter is for virtual socializing with friends and family, he says.

Rodolff suggest spending an hour a week on your LinkedIn profile or various components offered through the website.

“But depending what role LinkedIn plays in your promotional plan, it could be a lot more or a lot less,” he

says.

There are certain must haves for a LinkedIn profile and that includes a photograph, which is one of the requirements for achieving 100 percent profile completion, according to the web site’s standards.

“You definitely need a photo. That’s one of the easiest things to fix,” says Rodolff.

Punch up your profile headline, Rodolff advises. It deserves careful consideration because you want it to grab attention and encourage people to keep reading your profile. Craft your headline with keyword richness that will show up in a Google search and other search engines. If you need a little help, turn to Google and research your industry for extra suggestions on popular search terms.

If you want to shine a light on your talents and uncover hidden career opportunities, a good place to start is with a polished profile on LinkedIn

It’s also smart to take advantage of “apps” on LinkedIn, such as Box.net, that once downloaded allows you to add PDFs and other documents to your profile. This is especially useful for medical writers to showcase examples of their writing, says Rodolff.

LinkedIn offers additional functions that help users raise their profiles and reach out to others for industry news and discussion. A few examples are offered below.

- **Join a LinkedIn group** and contribute your ideas and opinions or questions, says Rodolff. You may even aspire to become a “top expert” for answering questions in your knowledge area. Experts are featured on the site’s Answer home page which can be accessed under the tab marked “more.”
- **Create a poll** (via the “more” tab) to discover what others are thinking about industry topics or as a way to learn more in a new job field you are considering.

If your manager says to you “I need you to dig in”, when communicating their expectations, what does that mean?

Above is a poll question taken directly from LinkedIn, but you can fashion your own to meet your needs. For example,

(continued on next page)

AMWA chapter members might want to poll the group to rank topics for the next meeting, says Rodolff. Then you may want to post an update on the poll results.

- **Posting updates** on LinkedIn is another way to reach out to your connections but some AMWA members agreed that it's a function that some use to annoying distraction.
- **Send one email to a select group of people**, an approach that Rodolff prefers over sending out updates. It can be done through the connections tab and can include up to 50 people.

Once you select all the people you want to send the message, click send a message and their names show up in "to" field. Then you can write a message to just those people you think will be interested in the particular topic you are addressing. It's a way to let people know more about you and what you've been doing without hitting them with a hard sell pitch, explained Rodolff.

###



Let's save the date! **Saturday March 16** marks the date when our chapter will welcome the academic community and other newcomers to come look us over at our annual outreach event. We are so fortunate that the prominent biopharmaceutical company Amgen will host the free event and provide complimentary lunch. Here is our chance to visit the Amgen campus in Thousand Oaks and meet with the movers and shakers from its many writing groups. The event, organized by Aaron Van Etton, promises to be a dynamic day packed with presentations by excellent speakers who will cover a broad range of topics; journal publications, regulatory writing, grants, freelancing, medical communications, and breaking into the career of medical writing. Also planned are several lunchtime roundtable discussions focusing on networking, how to develop a portfolio, and life-work balance.

Please stay tuned for more information. In early February, an announcement of the event, together with directions and a map will arrive in your e-mail box. Reservations will be required, so be sure to sign up early. This will be an exciting event not to be missed.

Pictures from the AMWA Pac-SW Holiday Party, December 2012

Meet my friend C.A.R.L.

By Irene Yau, Allergan Inc.

If you find yourself needing to update your resume or prepare for a job interview, remember my friend C.A.R.L., a neat acronym that is applicable to many aspects of a job preparation. I've found this to be an effective way to prepare for job interviews and craft resumes.

Start by making a list of your previous jobs or experiences and then making four columns next to each experience with the following headings in each column:

C = Challenge or Context

A = Action

R = Results

L = Learn

Challenge or **C**ontext

Brainstorm and write in this column a few of the most impactful challenges, problems, or situations you were involved in at each of your previous jobs. For example, the context of this situation could be that the team needed training to remain compliant with FDA regulations, but the budget just did not allow for sending everyone for training.

Action

This column is where you describe what you actually did to remedy the situation. You can give details concerning the actual steps that you took to solve the problem

described above. In our scenario, let's say that you did research and found an online course that is cheaper, but it provides the same quality of training. What you've described sounds impressive, but stopping the story here would be a huge mistake and you would only be telling half of the story.

Results

In this section of the story, you state the results of the actions you took. Employers care about results. You could be busy doing one hundred things, but they need to produce a tangible outcome or contribute to the company's goals. The result of researching and finding an alternative training method would be that all 12 team members were trained, saving \$50k in expenses, and freeing up 100 work-hours that would have been lost to travel time.

Learned

I would call this the bonus section or the "cherry on top". You've already effectively given a complete story, but you can go one step further by adding what you've learned from this situation. For example, you could have learned in the fictional scenario above that there's always an alternative solution even if the solution is not conventional.

Source: University of California, San Diego Career Services Center. Joe Cribari

Job/Experience	CHALLENGE	ACTION	RESULT	LEARNED
1. XYZ Pharmaceuticals	no budget for team training	Researched/found an online training course	12 entire team trained, \$50k savings, 100 free hours	Always alternative solutions, non conventional solution



AMWA Pacific Coast Conference

(April 28 – May 1, 2013)

Asilomar Conference Grounds

800 Asilomar Blvd

Pacific Grove, California 93950

www.visitasilomar.com

Medical Communications: Expand Your Reach and Focus Your Skills

Join us for 3 days of small-group workshops, fireside forums, and provocative conversations with writers, editors, scientists, and other medical communicators in the beautiful, relaxing retreat setting of the Asilomar Conference Grounds. Here's just a taste of the forums.

- Regulatory documents for the non-regulatory writer
- Conducting successful document review meetings
- Technical tricks for efficient reviews and revisions
- Good publication practices
- Medical communications careers (panel discussion)

...and more!

Keynote Session: Globalization's Impact upon Health in the Developing World, by Michele Barry, M.D., F.A.C.P; Senior Associate Dean for Global Health/Director Global Health Initiatives, Stanford University

Take advantage of this rare opportunity to take an Advanced workshop at a Chapter conference.

Workshops

- Essential Ethics for Medical Communicators (ES) [2006], Cindy Hamilton
- Business Aspects of a Freelance Career (B/FL) [2500], Cindy Hamilton
- Summarizing Clinical Efficacy Data for a New Drug Application (RR) [4013], Peggy Boe
- Reporting Randomized Trials in Science Journals (ADV) [719], Tom Lang

NEW!! 2013 PACIFIC-SOUTHWEST ASILOMAR AWARD

Established to support ongoing education of medical writers, the award recipient will receive free conference registration. All current/aspiring medical writers are welcome to submit an entry. For more information and an entry form, visit the Pacific-SW Chapter Website. Entries due by January 31, 2013. Winner announced February 15, 2013.

Additional conference information available online at
http://www.amwa-pacsw.org/events/PCC_2013/index.html



Four Sporting Boys: Basketball



"Four Sporting Boys: Basketball," 1949, watercolor, 13.5" x 12". By Norman Rockwell, 3 Feb 1894 – 8 Nov 1978.

Location: Norman Rockwell Museum, Stockbridge, Mass; loaned by Williams High School Alumni Association.

During February, college basketball teams will shuffle around the board and soon our nation will be in the grips of March Madness. February is also the month of 20th century's most beloved American painter and illustrator, Norman Rockwell.

Norman Percevel Rockwell was born on February 3rd, 1894, in New York City. At six feet and just 140 pounds, unathletic by his own accounts, he took to drawing as his escape and passion. Before he was 16, he was commissioned to create a set of four Christmas cards, and at age 18 he became the art editor of *Boy's Life* (the publication of Boy Scouts of America). Norman Rockwell painted small-town America living the American dream. Most of his famous paintings appeared as covers of *The Saturday Evening Post*, 321 covers in all over 47 years until 1963. His work depicted people from his hometown of Arlington, Vermont, and life as he saw it. He was also commissioned to do portraits of US Presidents Eisenhower, Kennedy, Johnson and Nixon, and foreign leaders including Nehru.

His life work includes over 4000 works of paintings, illustrations and drawings, most of which were published as magazine covers, illustrated books, calendars, advertisements, etc. He was among the most licensed artists in this country. Norman Rockwell museum (www.nrm.org) in Stockbridge, Mass., houses the largest collection of Norman Rockwell's work.

—Editor